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MS: PCT

Attorney Docket No.: 27252U

Date: May 11, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ULRICH

Art Unit: Unknown

Examiner: Unknown

Appl. No.: 10/573,525

Filed: March 24, 2006

Intl. Appl. No.: PCT/EP2004/052376

Intl. Filing Date: September 30, 2004

For: **IMIDAZOPYRIDINE-DERIVATIVES AS INDUCIBLE NO-SYNTHASE
INHIBITORS**

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

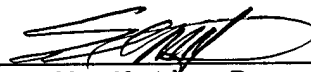
Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Submission of Documents to Supplement Filing Documents under 35 USC 371;
- 2) PCT/IB/373 (International Preliminary Report on Patentability);
- 3) PCT/ISA/237 (Written Opinion of the International Searching Authority).

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC



Gary M. Nath, Reg. No. 26,965
Sheldon M. McGee, Reg. No. 50,454
Customer No. 34375

NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

GMN/SMM/le



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SUBMISSION OF DOCUMENTS
TO SUPPLEMENT FILING DOCUMENTS UNDER 35 USC 371

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Sir:

In order to supplement the filing documents for the national phase filing Under USC 371 commenced on **March 24, 2006** of the captioned application, applicant now submits the following documents:

- 1) PCT/IB/373 (International Preliminary Report on Patentability);
- 2) PCT/ISA/237 (Written Opinion of the International Searching Authority).

Please charge any deficiency or credit any overpayment to our Deposit Account Number 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC


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GMN/SMM/1e

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1226WOORD01	FOR FURTHER ACTION		See item 4 below
International application No. PCT/EP2004/052376	International filing date (<i>day/month/year</i>) 30 September 2004 (30.09.2004)	Priority date (<i>day/month/year</i>) 01 October 2003 (01.10.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ALTANA PHARMA AG			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> Box No. II | Priority |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report
03 April 2006 (03.04.2006)

Authorized officer

Yolaine Cussac

Telephone No. +41 22 338 70 80

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 740 14 35

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

REC'D 10 DEC 2004

WIPO

PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

01/04

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/052376

International filing date (day/month/year)
30.09.2004

Priority date (day/month/year)
01.10.2003

International Patent Classification (IPC) or both national classification and IPC
C07D471/04, A61K31/437, A61K31/444, A61P25/00, A61P29/00, A61P31/00

Applicant
ALTANA PHARMA AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Bosma, P

Telephone No. +31 70 340-3665



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/052376

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/052376

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/052376

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 15,16 with respect to IA

because:

- ☒ the said international application, or the said claims Nos. 15,16 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/052376

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-16
	No: Claims	
Inventive step (IS)	Yes: Claims	1-16
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 15 and 16 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following document are referred to in this communication:

D1 : WO 00/49015 A (TAKE KAZUHIKO ;FUJISAWA PHARMACEUTICAL CO (JP);
TOMISHIMA MASAKI () 24 August 2000 (2000-08-24)

Novelty and Inventive step

1) Document D1, which is considered to represent the most relevant state of the art, discloses **pyridine compounds** which are linked to a heterocyclic group such as a **benzimidazolyl group**. The compounds are having an inhibitory activity on the production of nitric oxide and are useful for the prevention and/or treatment of NOS (nitric oxide synthase)-mediated diseases.

From this, the subject-matter of the present claims differs in that the present application deals with **pyridin-2-yl-alkylene-3H-imidazo[4,5-b]pyridine** derivatives, which compounds are also having an inhibitory activity on the production of nitric oxide and are useful for the prevention and/or treatment of NOS (nitric oxide synthase)-mediated diseases.

The subject-matter these claims is therefore novel (Article 33(2) PCT)

2) The problem to be solved by the present invention may be regarded as the provision of further compounds that are having an inhibitory activity on the production of nitric oxide and are useful for the prevention and/or treatment of NOS (nitric oxide synthase)-mediated diseases.

The solution to this problem proposed in the claims of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The present specifically by Het1-substituted **imidazo[4,5-b]pyridine** derivatives of formula (I) are structurally very remote from any of the available prior art compounds having the same use and it is therefore considered that there were no incentives from this prior art to use the above described **pyridin-2-yl-alkylene-3H-imidazo[4,5-b]pyridine** derivatives as nitric oxide synthase inhibitors.

3) The statements in the description on page 20, third paragraph, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.

Industrial applicability

4) For the assessment of the present claims 15 and 16 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.